K082286

Graftys

BIOACTYS®
510(k) Summary

FEB 2 4 2009

Prepared: July 29, 2008

1. Submitter Information

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Contact:	Anthony LE NAOUR - Regulatory Manager

2. Name of Device

Trade Name:	BIOACTYS®
Common Name:	Resorbable calcium salt bone void filler device
Classification name:	Dental Bone Grafting Material Device (CFR 872.3920 ; Product Code : LYC)
Device panel	Oral/Dental

3. Legally Marketed Predicate Device

Predicate	MBCP ™ - Resorbable calcium salt bone void filler device [K051885]
	GRAFTYS®BCP- Resorbable calcium salt bone void filler device [K073064]

4. Device Description

BIOACTYS® is a sterile single use bioresorbable bone void filling substitute.
BIOACTYS® is a microporous and macroporous two-phase calcium phosphate ceramic made of 60% Hydroxyapatite and 40% beta-tricalcium phosphate.
Following placement in the bony voids or gap, BIOACTYS® resorbs and is replaced with bone during the healing process.
BIOACTYS® is available in the form of granules.

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5. Intended Use

BIOACTYS® is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region

6. Technological characteristics

BIOACTYS® and the predicate devices have the same technological characteristics. They are sterile single use devices made of 60% Hydroxyapatite/40% β-Tricalcium Phosphate and have a similar porous structure (total volume ratio of 70%) that promotes bone ingrowth by osteoconductivity. BIOACTYS® and predicates are provided sterile for single-use.

7. Non clinical performance data

In vitro tests, performed according to the Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices; Guidance for Industry and FDA Staff issued April 28 2005, support the substantial equivalence between BIOACTYS® and the predicate devices.

8. Conclusion

BIOACTYS® is claimed to be substantially equivalent in terms of safety and effectiveness to the predicate devices as a non structural osteoconductive bone void filler for osseous defect.

GRAFTYS – SARL au capital de 1 599 995 Euros – Siret 484 024 989 00028 – APE 244D
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Mr. Anthony Le Naour
Regulatory Affairs Manager
Graftys
Eiffel Park-Bât D
415, rue Claude Nicolas Ledoux
F-13 854 Aix en Provence Cedex 3
FRANCE

FEB 24 2009

Re: K082286
Trade/Device Name: Bioactys®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: February 12, 2009
Received: February 17, 2009

Dear Mr. Le Naour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K082286

Device Name:

Bioactys®

Indications For use:

Bioactys® is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

These defects may be surgically created osseous or defects created from traumatic injury to bone.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082286

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)